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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,340	03/23/2001	Bert Vogelstein	01107.00074	4414

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

15

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,340

Applicant(s)

VOGELSTEIN ET AL.

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 23 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of Paper No. 9 is withdrawn.
2. Claims 1-9 and 19-22 have been canceled. Claims 10-18 and 23 are pending and under consideration.
3. Sections of the text of Title 35 U.S. Code not found in this action can be found in a previous action.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 10-18 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claims 10-18 and 23 are vague and indefinite for reciting dependence upon the subject matter of a canceled claim. For purpose of examination, claim 10 will be read as having the subject matter of the canceled claim.
6. Claims 10-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Claim 10 is drawn to method of screening compounds to identify potential anti-cancer agents comprising contacting a test compound with each of the two isogenic cell lines of claim 5 and identifying as a potential anti-cancer agents a test compound which preferentially inhibits growth of the first cell line relative to the second cell line. Claim 11-15 embody the method of claim 10 wherein a test compound is identified as a potential anti-cancer agent if it inhibits the growth of the first cell line at least 2-fold, 5-fold, 10-fold, 20-fold and 50-fold more than the

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second cell line, respectively. Claim 23 embodies the method of claim 10 wherein the two isogenic cell lines are human cell lines.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The method objective of claim 10 is the identification of a potential anti-cancer agent. Thus, it would be expected that one of skill in the art would be able to identify an anti-cancer agent without undue experimentation by using the claimed method. The instant method specifies the contacting of a test compound with the disclosed isogenic cell lines. The specification does not teach a particular test agent which would inhibit the growth of the first cell line relative to the second cell line. The specification does not teach any structural or biochemical requirements which should be present in the genus of test compounds which would allow one of skill in the art to select a set of test compounds and subject them to the instant method with a reasonable expectation of success of identifying an agent which would inhibit the growth of the first cell line relative to the second cell line. Further, the specification does not teach a partial structure coupled with a biochemical characteristic which would provide a reasonable expectation of success to one of skill in the art for the selection of test agents which would inhibit the cell lines as claimed. Given the lack of guidance in the specification for how to find a test agent which would function as claimed, one of skill in the art would be subject to undue experimentation in order to carry out the claimed methods.

7. Claims 10-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention..

The instant method claims are reliant upon a genus of test compounds. The genus is highly variant because it encompasses a molecule of any structure. The specification does not any written description of a single test agent which would function in the claimed method.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43

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USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court also stated that

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *Id.* At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. V. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

In this case, the specification does not describe the test agents in a manner that satisfies either the Lilly or Enzo standards, because it fails to describe a single test agent, or a partial structure of a test agent coupled with physical or chemical characteristics. Method claims lack adequate written description when they dependent upon a product which is not adequately described. One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention.

8. The findings in *University of Rochester v G.D. Searle & Co*, 249 F. Supp. 2d 216 (W.D.N.Y. 2002), and 358 F.3d 916, 69 USPQ.2d 1886 (BNA) (Fed Cir Feb 13, 2004) are relevant to the instant claims. The Federal Circuit upheld the decision rendered from United States District Court regarding the invalidity of U.S. 6,048,850. The claims in the '850 patent

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were drawn to methods for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of PGHS-2. The District Court determined that the '850 patent was invalid because it did not provide an enabling disclosure of how the invention was to proceed. The court concluded that although the patent provided an assay for identifying selective PGHS-2 inhibitors, and teachings for how to use such compounds once identified, the patent lacked the "necessary link" between the two stages, because it did not teach how to find a compound which actually worked as a selective inhibitor. The court concluded that the patent gave "previous little guidance" on how to find such a suitable compound. The court states that "at most, its description will enable a person of ordinary skill in the art to attempt to discover [original emphasis] how to practice the claimed invention. That is not enough". Further, the District Court addressed the application of the written description requirement in regard to the method claims and determined that the '850 patent did not satisfy the written description requirement, citing the decisions in Lilly and Enzo. The court stated that the '850 patent did no more than describe the desired function of the compound required for the method. The court concluded that the patent did not succeed in taking the last critical step of actually identifying a suitable compound, or at least developing a process through which one of skill in the art would be directly led to such a compound.

The claims at issue in the *Rochester v Searle* are similar in nature to the instant invention. The instant specification teaches a method to assay of cell growth using the disclosed isogenic cell lines. The specification provides teachings on how to use the test compound once it is identified as a selective inhibitor of the first isogenic cell line. The specification does not provide the necessary link between the two stages because it does not teach how to find a compound which actually works as a selective inhibitor. It is concluded that the specification gives no guidance at all on how to find a suitable compound without undue experimentation.

9. All other rejections and objections as stated or maintained in the previous Office action are withdrawn.

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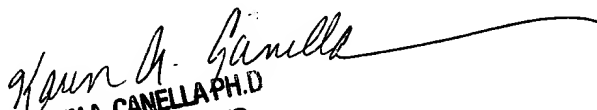
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828.

The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
11/9/2004


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER